UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

FEB 2 8 2006

MEMORANDUM

SUBJECT: Secondary Scientific Review of Storage Stability With Corrosion Characteristics Study on EPA Reg. No. 80518-1, Rouse

FROM: Carol E. Frazer, Ph.D., Toxicologist Carol
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Biopesticides and Pollution Prevention Division (7511C)

TO: Denise Greenway, Regulatory Action Leader
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Submission Contents:

- The completion of the storage stability with corrosion characteristics study on Rouse (EPA Reg. No. 80518-1) Chemicals 911647, 46701, 43801; D#363058, DP# 324658, MRID 467021-01

- Product contents – 0.05% 6-benzylaminopurine (6-BA), 0.05% gibberellic acid (GA_3), 0.09% indole-3-butyric acid (IBA), and 99.81% other ingredients

Action Requested:

On 29 November 2005, in behalf of CytoTek Enterprises, Inc., Michael Kellogg of Pyxis Regulatory Consulting, Inc., submitted three copies of a completed storage stability study with corrosion characteristics on Rouse to complete registration.

This study's purpose was to determine stability and corrosion characteristics of the product Rouse in its commercial packaging or equivalent. Following one year's storage at 20° ± 2°C, and testing at 3, 6, 9 and 12 months, there were no significant problems. The only changes seen in the study were in the visual aspect of the product. Over the year's study, the appearance darkened from transparent yellow-orange to slightly cloudy orange to transparent dark orange with small particles on the bottom of the container. However, there were no changes in the test chromatograms indicating deterioration or degradation products. However, the chromatogram was not provided for review.

At the beginning, all three active ingredients were higher than the nominal concentrations given in the label, and in the case of IBA, higher than the upper limit given on the confidential statement of formulation (CSF). By the end of the study, 6-BA had essentially not been reduced at all, and the levels of the other two compounds were still equal to or above nominal concentrations.

Corrosion characteristics were evaluated by examining the physical appearance and weight of the container and a "coupon" of container material immersed in the product. Neither the physical appearance or weight of the 250 ml HDPE semi-transparent container with screw-top lid or the coupon were affected by the study.

Conclusions:

The submitted study is acceptable to satisfy both OPPTS §§ 830.6317 (storage stability) and 830.6320 (corrosion characteristics) No further data is required.

DATA EVALUATION RECORD

Primary Reviewer: Nasrin Begum, PhD Signed: January 28, 2006
Tetrahedron Contractor
EPA Secondary Reviewer: Carol E. Frazer, Ph.D. Date: February 27, 2006

Data Evaluation Record

STUDY TYPES: Supplemental Product Chemistry

DP BARCODE: 324658

P.C. CODES: Gibberellic acid: 043801; 6-Benzylaminopurine: 911647; Indole-3-butyric acid: 046701

SUBMISSION CODE: Reg. No. 80518-1

TEST MATERIAL: ROUSE

SYNONYMS: None

MRID No(s).: 467021-01

CITATIONS: Kaminisky, M. (2003). Storage Stability with Corrosion Characteristics. Data Requirements - Product Properties - OPPTS Series 830, ; Storage Stability - 883.6317; Corrosion Characteristics-830.6320. StillMeadow, Inc 12852 Park One Drive, Sugar Land, Texas. August, 2003. MRID 467021-01. Unpublished.

SPONSOR:
Cytotek Enterprises, Inc.
25414 Sugar Valley Lane
Spring, TX 77373

SUMMARY: ROUSE is a plant growth regulator and is used in Apples and non-food plants such as ornamental plants, ornamental trees, shrubs, and turf. This report has the findings of a study conducted to determine the stability and corrosion characteristics of the test substance, ROUSE, in a storage container for one year. Compared to the baseline measurement, the mean

concentration of the active ingredients were within acceptable levels, indicating stability. No evidence of corrosion was noticed in the packaging material.

COMPLIANCE: A dated, signed statement is included indicating that the study did comply with USEPA, Good Laboratory Practices (GLPs) FIFRA 40 CFR 160 and TSCA 40 CFR 792. A dated and signed statement of no data confidentiality claim is provided. A dated and signed statement of quality assurance is also provided.

I. MATERIALS AND METHODS

A. Materials

Test Substance:	ROUSE
Label identification:	ROUSE
Physical Description:	clear yellow brown liquid
Date & Amount received:	22 Mar 04; 1 gallon
Storage conditions:	Ambient conditions
Reference Substance 1:	Gibberellic acid CAS #77-06-5
Label identification:	Sigma, Gibberellic acid GA3 Content: At least 90% total gibberellins [77-06-5]
LOT#:	092K1097
Physical Description:	White Powder
Date & Amount received:	03 Sep 03; 1 gm
Storage conditions:	Ambient conditions
Reference Substance 2:	6-Benzylaminopurine
Label identification:	Aldrich,852430-1G-A 15411MO 6-Benzylaminopurine, 99% CAS#1214-39-7; FW 225.26
LOT#:	Not provided
Physical Description:	White powder
Date & Amount received:	03 Sep 03; 1 gm
Storage conditions:	Room temperature
Reference Substance 3:	Indole-3-butyric acid CAS #133-32-4
Label identification:	Sigma, Indole-3 butyric acid > 99%
LOT#:	102K1409
Physical Description:	Light tan powder
Date & Amount received:	03 Sep 03; 5 gm
Storage conditions:	Room temperature

B. Methods

Test Sample Methods: The test substance was observed physically as well as analyzed by UV-HPLC analysis using certified reference standards and calibration curves to obtain a baseline reference point. The test samples and active ingredients were prepared for observation at 3, 6, 9, and 12 months of storage. The samples were weighed and placed in an incubator at 20 degrees C (plus or minus 2 degrees C) storage condition. At each subsequent storage period the test samples were physically observed, and active ingredients were analyzed by UV-HPLC and compared to the baseline result.

Corrosion Characteristics: The containers were made up of semi-transparent 250-mL HDPE with screw-top lids. Two coupons of each stability samples were cut from the container material, weighed, and physically observed to get a baseline reference description, and then were immersed in the test substance.

II. DATA COLLECTION AND EVALUATION

Samples were collected and evaluated for physical changes and, ROUSE was also evaluated for changes in active ingredient content at 3, 6, 9, and 12 months. At each observation period, storage samples were evaluated and the 2 immersed coupons were removed, cleaned, dried, and weighed and evaluated.

III. RESULTS

The substance was initially found to be a yellow-orange transparent liquid, bubbled when shaken and has a slight isopropyl alcohol odor. The test substance darkened to an orange cloudy liquid at the six month stage and regained transparency, but darkened to dark orange with small particles at the bottom at month 12.

Storage Stability Samples

The only observed changes after 3, 6, 9, and 12 months were minimal (-0.05%, -0.09%, and -0.08%, and -0.08% respectively) changes in weight.

The percent change of gibberellic acid, one of the active ingredients at 3, 6 9, and 12 months was 0.056, 0.057, 0.053, 0.50 respectively. The percent change of 6-benzylaminopurine, another one of the active ingredients at 3, 6, 9 and 12 months was 0.055, 0.52,0.053 and 0.55 respectively. The percent change of indole-3-butyric acid, one of the active ingredient at 3, 6, 9 and 12 months was 0.104, 0.105, 0.104 and 0.098 respectively. There was no baseline value. The percent active ingredient changes are reasonable for laboratory technique, sampling and instrument variations over time.

It was stated that there were no changes in chromatograms indicative of development of deterioration. However, no chromatograms are provided in the study report.

Corrosion Characteristics Samples:

Physical changes were not observed in the test containers. There was an increase in weight in the coupons tested during the 3, 6, 9, and 12 month period. The mean increases were +0.0%, +0.02%, +0.13%, 0.09% respectively for the 3, 6, 9, and 12 month period. The control coupon's net increase in weight was 0.11%.

Table 1 Physical Descriptions
Storage Stability and Corrosion Characteristics
Test Substance: Rouse

Observation Period	Test Substance	Test Container/Test Coupon
Month 0 (Baseline - Day 0)	Yellow-orange color with slight isopropyl alcohol odor. Liquid forms bubbles when shaken. Liquid is transparent.	250-mL HDPE semi-transparent containers with screw-top lids. Coupons made from same material. Coupon 1 - No Seam. Coupon 2 - Seam.
Month 3	No change from baseline	No change from baseline in container or coupons
Month 6	Orange color with isopropyl alcohol odor. Slightly cloudy.	No change from baseline in container or coupons
Month 9	No change from baseline	No change from baseline in counter or coupons
Month 12 (termination)	Dark orange color with isopropyl alcohol odor. Liquid is transparent with small particles on bottom of container.	No change from baseline in container or coupons

Table 2: Active Ingredient Analysis
Storage Stability and Corrosion Characteristics
Test Substance: Rouse

Observation Period	Gibberellic acid		6-Benzylaminopurine		Indole-3-Butyric acid	
	% Conc	% Var[1]	% Conc	% Var[1]	% Conc	% Var[1]
Label Claim	0.054	NA	0.051	NA	0.093	NA
Month 0 (Baseline)	0.0548	NA	0.0553	NA	0.1049	NA
Month 3	0.0556	1.45	0.0547	-1.08	0.104	-0.86
Month 6	0.0574	4.74	0.0519	-6.15	0.1048	-0.1
Month 9	0.053	-3.28	0.0528	-4.52	0.104	-0.86
Month 12 (termination)	0.0504	-8.03	0.0552	-0.18	0.0982	-6.39
Statistics:	X_n= 0.054% $\acute{o}_{n-1}$= 0.003% RSD=4.92%	Range = 0.007 ± 0.004	X_n= 0.054% $\acute{o}_{n-1}$= 0.002% RSD=2.85%	Range = 0.003 ± 0.002	X_n= 0.103% $\acute{o}_{n-1}$= 0.003% RSD=2.73%	Range = 0.007 ± 0.003

Table 3: Weight Change Evaluation
Storage Stability and Corrosion Characteristics
Test Substance: Rouse

Weight of Test Substance

Observation Period	Initial (Month 0) Weight (g)	Terminal Weight (g)	Difference (g)	Gain/Loss (%)
Month 3	262.5037	262.385	-0.1187	-0.05
Month 6	266.8465	266.6128	-0.2337	-0.09
Month 9	279.9436	279.7147	-0.2289	-0.08
Month 12 (termination)	267.5272	267.3382	-0.189	-0.08

Table 3 Continued.....
Weight of Corrosion Coupons

Observation Period	Initial Weight (g)	Terminal Weight (g)	Difference (g)	Gain/Loss (%)	Mean (%)
Control	0.5586	0.5592	0.0006	0.11	0.11
	0.7904	0.7913	0.0009	0.11	
Month 3	0.4956	0.4956	0	0	0
	0.772	0.772	0	0	
Month 6	0.3801	0.3802	0.0001	0.03	0.02
	0.7872	0.7873	0.0001	0.01	
Month 9	0.3638	0.3645	0.0007	0.19	0.13
	0.6087	0.6091	0.0004	0.07	
Month 12 (termination)	0.3885	0.3889	0.0004	0.1	0.09
	0.8102	0.8108	0.0006	0.07	

IV. DISCUSSION.

The quality control data for analytical method is not adequately provided in this report. No chromatogram is provided in this report. Environmental parameter, such as humidity is not mentioned either.